

Introducing New HIV Prevention Technologies: The Example of the Female Condom

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ABSTRACT

With an estimated 34 million people living with HIV in 2011, HIV remains a major public health issue (Joint United Nations Programme on HIV/AIDS, 2012). In response, researchers are working to develop a range of new prevention technologies (NPTs)—including microbicides, pre-exposure prophylaxis (PrEP), and vaccines—each of which will need to be strategically introduced in order to ensure high levels of uptake and, in turn, a significant impact on the HIV epidemic. However, the introduction of prevention technologies can prove challenging.

In the early 1990's the female condom—the first female-initiated prevention technology—offered the hope of lowering HIV and STI infection rates while providing an additional contraceptive choice to the millions of women who lacked access to contraception (Pathfinder, n.d.). In a few settings the female condom was integrated into family planning and other services and enjoyed high levels of acceptance and uptake. In most others female condoms were marginalized and never made it into the mainstream. Overall, more than 20 years after their initial introduction, female condoms are still not used as widely as they should be as a way to prevent HIV and unwanted pregnancy and constitute a missed opportunity for the public health field.

As the HIV prevention field looks toward a generation of new prevention technologies, important lessons for their eventual introduction can be garnered from the experience of the female condom. By examining female condom success stories, such as those from South Africa and Zimbabwe and disappointments, like the introduction of female condoms in the United States, program planners can strategically design informed introduction efforts, increasing the likelihood they will have a significant public

health impact. This paper offers a range of lessons and recommendations for public health practitioners seeking to design programs for the introduction of NPTs. Some of these lessons include the need to:

- engage communities and the advocacy community,
- focus on education and training including that of end users' sexual partners,
- carefully select target populations,
- integrate NPTs into existing health services and programs,
- ensure strong leadership,
- negotiate the end cost of products,
- expand distribution systems, and
- continually monitor and evaluate programs.

GLOSSARY

AIDS: acquired immunodeficiency syndrome
ARV: antiretroviral
CE mark: European Conformity mark
CHANGE: Center for Health and Gender Equity
FC1: FC1® Female Condom
FC2: FC2® Female Condom
FDA: US Food and Drug Administration
FHC: Female Health Company
FHF: Female Health Foundation
GCWA: Global Coalition on Women and AIDS
HIV: human immunodeficiency virus
M&E: monitoring and evaluation
MCC: South Africa Medicines Control Council
MoH: Ministry of Health
NGO: nongovernmental organization
NPT: new prevention technology
PEPFAR: President's Emergency Plan for AIDS Relief
PrEP: pre-exposure prophylaxis
PSI: Population Services International
STI: sexually transmitted infection
UNAIDS: Joint United Nations Programme on HIV/AIDS
UNFPA: United Nations Population Fund
UNHCR: Office of the United Nations High Commissioner for Refugees
UNICEF: United Nations Children's Fund
US: United States
USAID: United States Agency for Development
WHO: World Health Organization

INTRODUCTION

It is well known that HIV remains as a major global public health issue. In 2011, an estimated 34 million people were living with HIV, with 7,400 people becoming newly infected every day (Joint United Nations Programme on HIV/AIDS, 2012). Due to a combination of factors, including unequal access to education; a greater physiological vulnerability; widespread gender based violence; and a limited capacity to negotiate sexual decisions, women face greater barriers in preventing and treating HIV and are therefore disproportionately affected by the epidemic (UNAIDS, 2012). In fact, young women (ages 15 to 24) are the most at-risk with infection rates twice as high as their male counterparts (United Nations Children's Fund, 2011).

In response, the last several decades have seen a move toward combination prevention strategies, with behavior change, condom promotion, structural interventions, biomedical research, and universal treatment efforts each playing their part (United Nations Population Fund, World Health Organization & PATH, 2005). In the biomedical field, researchers are working to develop a range of new prevention technologies (NPTs) including microbicides, pre-exposure prophylaxis (PrEP), and vaccines. While male condoms have been in use for centuries, and for more than 80 years in their current latex form, the fact remains that many people are unable or unwilling to use male condoms and a greater range of prevention options is vital (Youssef, 1993). If these new technologies are to have any significant public health impact, introduction efforts need to be well planned and draw on the lessons learned of past introduction efforts.

In the 1990s, such an introduction effort took place around the female condom.

The female condom emerged on the scene as the first female-initiated prevention device that could offer protection against HIV, as well as other sexual transmitted infections (including those that contribute to HIV vulnerability) and pregnancy. In addition, the female condoms offered a range of unique advantages including addressing gender inequalities and aiding women who have a difficult time negotiating the use of male condoms (Forbes, 2012; Global Coalition on Women and AIDS, n.d.).

However, despite a few success stories, the initial introduction of the female condom constituted a public health intervention failure in many places. In settings where the female condom enjoyed success, it was integrated into family planning and health services and, in turn, enjoyed high levels of acceptance and uptake. In others, female condoms were marginalized and still have not made it into the mainstream. Overall, more than 20 years after their initial introduction, female condoms are still not used as widely as they should be as a way to prevent HIV and unwanted pregnancy. This constitutes a missed opportunity for the public health field.

As the HIV prevention research field moves toward introduction efforts around a potential range of NPTs it is worth exploring the uneven experience of the female condom. This paper examines the experience of the female condom in order to draw lessons learned for the eventual introduction of other novel HIV prevention technologies.

BACKGROUND

A thin sheath inserted by a woman into her vagina before sex (or inserted anally by a man or woman for protection during anal sex), the female condom is the first HIV

and STI prevention device designed for a woman to use without her partner's active involvement. While numerous studies have shown that many women will still require their partner's consent to use a female condom and/or will choose to disclose their use of the female condom (Hoffman, Mantell, Exner, & Stein, 2004), female condoms expand the range of prevention options available and provide a device that women can initiate and insert well before sexual intercourse. Further, the female condom remains the only HIV prevention alternative to the male condom that offers the extra benefit of protection against unwanted pregnancy.

When first introduced, the female condom offered great hope in the fight against HIV. Increasing the number of sex acts that are protected is the key to reducing sexual transmission of HIV, and expanding the range of prevention options available is one of the most promising ways of achieving greater rates of protection (GCWA, n.d.).

The history of the female condom and the Female Health Company

In 1984, just three years after the HIV epidemic was uncovered, Lasse Hessels—a Danish doctor—invented the female condom (Peters, Jansen, & van Driel, 2010). Soon after, Hessels traded the rights to market the female condom in North America to the US-based Wisconsin Pharmacal Co., Inc. in exchange for their developing the product to meet the US Food and Drug Administration's (FDA) requirements for approval (Frost, Reich & Pratt, 2008).

Before a drug or medical device can be marketed and distributed in a country it must be approved by the recognized regulatory agency. In the United States, this is the FDA. In Europe, medical devices are approved with the European Conformity (CE) mark while the European Medicines Agency (EMA) evaluates medicines. Some other

countries have their own regulatory bodies such as the Indian Drug Authority and the South African Medicines Control Council (MCC), while others follow the rulings of some of the more established regulatory bodies like the FDA, EMA or MCC.

With the backing of women's health advocates, Wisconsin Pharmacal's new, dedicated division, the Female Health Company, finally gained FDA approval for the female condom in 1993 (Peters et al., 2010). The uncharacteristically long regulatory process was due in part to a change in FDA requirements for medical devices. In 1988, "the FDA made a decision to use stricter criteria to evaluate all new condoms...requiring more extensive safety and efficacy studies" (Frost, Reich & Pratt, 2008, p.169).

Meanwhile, faced with financial difficulties and regulatory delays, Hessels sold the world rights to the female condom to a Dutch investor who established Chartax Resources, Ltd., a London-based company to manufacture the female condom. Chartax quickly gained regulatory approval to market the device in a number of countries outside North America (Frost, Reich & Pratt, 2008). In 1995, the Female Health Company acquired Chartax and with it the exclusive rights to manufacture and market the female condom worldwide (Frost, Reich & Pratt, 2008).

The Female Health Company's first generation female condom, the FC1 Female Condom®, was primarily distributed in areas with populations at high risk for unintended pregnancy and sexually transmitted infections (The Gray Sheet, 1993). Representing an improved design, the Female Health Company's second-generation condom, the nitrile FC2 Female Condom®, has since replaced the earlier polyurethane FC1. The FC1 and FC2 remain the only FDA approved female condoms and are currently the only female condoms available in the United States. In addition, the Female Health Company is the

only female condom manufacturer that has had their female condoms approved by the World Health Organization's (WHO) pre-qualification system (Peters et al., 2010).

Without the backing and approval of the WHO, products are not distributed by United Nations agencies like the United Nations Population Fund (UNFPA) or other public donors that follow WHO guidelines (Peters et al., 2010). As these agencies and donors distribute the bulk of subsidized public health goods worldwide, their support is vital for the widespread success of any product.

Today, due to its approval by the FDA and WHO pre-qualification status, the Female Health Company's FC2 Female Condom® is the most widely available female condom (Female Health Company, n.d.). It is also the brand of female condom primarily used by global health and development agencies and other public donors distributing the female condom for free or at a subsidized cost via public health projects and research studies. Yet despite its near monopoly on the female condom, the Female Health Company is a small company with one dedicated product that has been plagued by financial difficulties (Frost, Reich & Pratt, 2008). These difficulties are in part due to the low uptake of the female condom and its relatively high price. The company is working with partners toward price reduction. Unlike large pharmaceutical companies who trade in high grossing drugs and medical devices, the Female Health Company is in the business of delivering a public health good. In fact, according to the company, their main market is the public health sector, which distributes the FC2® for use in prevention and family planning programs at reduced bulk pricing (Female Health Company, n.d.). So while the Female Health Company does provide some education and training materials to providers and distributors, the main drivers of female condom

promotion are the public health and family planning agencies with which the company and its foundation partner.

Other female condom products

In addition to the FC1 and FC2 Female Condoms®, two additional products have emerged on the market—the Cupid® Female Condom and the Woman's Condom (Forbes, 2012). Since neither of these products has yet been approved by the FDA, they are exclusively manufactured and sold outside of the US.

The Cupid® Female Condom, another second generation product, is similar to one formerly produced by Medtech Products Ltd. and sold under a variety of brand names including the Reddy female condom, V-Amour, L'amour, and the VA w.o.w.® Feminine Condom (Center for Health and Gender Equity, n.d.; Forbes, 2012). Now produced by Cupid, Ltd., the latex Cupid® Female Condom has been approved by the Indian Drug Authority and given the European Conformity (CE) mark by European regulators, allowing it to be sold throughout the European Union and used by European public-sector agencies (Forbes, 2012; Frost, Reich & Pratt, 2008). The Cupid® Female Condom is currently being sold in India, Brazil, Portugal and South Africa (Forbes, 2012).

The Woman's Condom, is gathered into a unique geletin capsule for easy insertion. The capsule dissolves rapidly (in less that a minute) inside the body allowing the condom to expand and line the vagina. It is manufactured by the Shanghai Dahua Medical Apparatus Company, based in China (Forbes, 2012). Approved by European and Chinese regulators in 2010 and 2011 respectively, the Woman's Condom is in its early distribution phase in China and South Africa (PATH, n.d.). PATH, a global health

organization and the original creator of the Woman's Condom, is simultaneously working to gain pre-qualification approval for the Woman's Condom from the WHO and expand the condom to developing country markets.

Early introduction efforts

The Female Health Company first introduced the female condom in Switzerland in 1992 (Frost, Reich & Pratt, 2008). In 1993, after receiving approval by the FDA, European authorities and regulatory agencies in 11 other countries, the Female Health Company began selling the female condom and supplying them to public agencies (Frost, Reich & Pratt, 2008). Introduction of the product began in a number of markets, with varying degrees of success. Since the female condom was a new product, completely unfamiliar to the public, program planners set out to generate initial interest in it among a range of stakeholders including governments, women's groups, local and international nongovernmental organizations (NGOs), bilateral institutions, and public and private funders. Depending on the anticipated market, planners and the manufacturer involved a combination of these actors in a variety of strategies to introduce the female condom with the hopes of lowering rates of HIV, STIs and unwanted pregnancy (Hoffman et al., 2004). Some of the strategies used included social marketing campaigns; provider education and training; and coordination with Ministries of Health (MoH) and national family planning and HIV/AIDS planning bodies (UNFPA, WHO & PATH, 2005).

In 1996, the Female Health Company established the Female Health Foundation to work alongside UN agencies, NGOs and national governments to promote the female condom through various global women's health projects (Frost, Reich & Pratt, 2008).

While the foundation and its partners saw advances in a few countries where the female condom was actively promoted, most early introduction efforts achieved little success (Frost, Reich & Pratt, 2008). Introduction efforts took many forms; from public and commercial distribution to full blown social marketing campaigns. (Hoffman et al., 2004). Most, however, consisted of small pilot projects, “characterized by a lack of funding and strategic planning to identify a target audience, train providers or do outreach to potential users “ (Warren & Philpott, 2003).

Condom introduction in places like the US and Europe, by their very nature, did not include the support from the global health and development communities that was part of some of the developing world efforts. Spurred primarily by the Female Health Company—a small company facing financial difficulties—female condom introduction in the US and other developed world markets was instead characterized by limited advertising and promotion and inadequate distribution within the public health systems (Hoffman et al., 2004; Frost, Reich & Pratt, 2008). As noted by public health experts Susie Hoffman, Joanne Mantell, Theresa Exner and Zena Stein (2004, p. 141), a major lesson from the female condom experience, “is that introduction does not mean simply putting the female condom on the pharmacy shelf. Rather, it requires proactive, well-planned strategies.”

The second wave of introduction efforts

In response to the uneven success of early introduction efforts, a number of initiatives were launched. Beginning in 1999, the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the Female Health Company joined forces with ministries of health and various NGOs to implement female condom promotion programs in 17

countries (Warren & Philpott, 2003). In 2005, UNFPA launched the Global Female Condom Initiative to scale-up female condom programming in 23 developing countries. While both initiatives enjoyed some local success, they have not yet served to significantly alter the fate of the female condom. For instance, despite the Global Female Condom Initiative's achievement in nearly doubling the number of female condoms distributed in Africa in just three years, they have not been able to help countries establish reliable national distribution systems (Peters et al., 2010). Some advocates have also criticized UNFPA's strategy as one that perpetuates the notion that the female condom is a niche product, appropriate for only select groups of high-risk women instead of a generalizable public health good (Peters et al., 2010). In the end, after various introduction efforts in at least 90 countries over the past 21 years, female condoms are still not generally accessible in most countries (UNFPA, 2011).

What acceptability research told us and continues to tell us

Over the years, many have questioned whether the arguable failure of female condom uptake is simply due to the product being inherently unacceptable to women and their partners. However, acceptability studies conducted in a wide range of countries, and at different points throughout the research cycle, found good initial acceptability of the female condom, ranging anywhere from 37 to 96 percent (FHI360, 2007; NAM, n.d.a). A meta-analysis of over 40 early acceptability studies from a range of cultures and settings found the female condom acceptable to, on average, 50 to 70 percent of women and men surveyed (GCWA, n.d.).

Among other benefits, women reported feeling more control over their own sexual health; a greater ability to negotiate and ensure safer sex; and enhanced sexual

pleasure for both themselves and their partners (NAM, n.d.a; Population Council & Liverpool VCT, Care & Treatment, 2009)

In one acceptability study, conducted in 1999 in the United States among women attending an STI clinic in Alabama, female condoms were initially used (after their introduction and promotion) by participants in about half of their protected sex acts (Artz et al., 2000). While female condom use declined over the course of the six-month study, they were still used in over one-third of all sex acts twelve months after the start of the study (Artz et al., 2000; NAM, n.d.a). What's more, "of the women who used female condoms, 75% also used male condoms, showing that female condoms are generally used to increase choice and flexibility rather than as a total substitute for male condoms" (NAM, n.d.a).

In another acceptability study conducted in Tanzania, researchers explored participants' intention to use the female condom after a mass-marketing campaign. In the study, women reported that they were highly likely to use female condoms in casual situations but less likely to use them with regular partners, and unlikely to use them with their husbands (NAM, n.d.a). Male partners, by contrast, said they were likely to use female condoms with their wives or regular partners but much less likely to use them with casual partners (NAM, n.d.a).

Studies conducted by the WHO, the Female Health Company, Population Services International (PSI), FHI 360 (then Family Health International), and the International Planned Parenthood Federation found that women reported improved communication with their partners when they introduced female condoms into their stable relationships (GCWA, n.d.).

What this tells us is that men and women, in a range of settings, generally find the female condom acceptable and, in many instances, have discovered unique benefits to its use. Moreover, while some concern has been expressed over the years that promotion of female condoms—or any other NPT—would result in male condom migration (i.e., a decrease in the number of male condoms used), the introduction of female condoms has been shown to increase the number of overall protected sex acts—the key to reducing sexual transmission of HIV. In fact, as Hoffman, Mantell, Exner and Stein (2004, p. 141) observe:

“The potential of the female condom does not depend on its being the method of choice for the majority of women, or on its being more popular than the male condom. Decades of contraceptive research show that expanding the range of options increases the likelihood that each woman will find an acceptable method.”

But the question remains, if user preference is not the reason for female condom’s lack of popularity, what is? According to Peters, Jansen and van Driel (2010, p. 121), “acceptability may be determined as much by how the technology is introduced as by its physical characteristics.”

FACTORS ASSOCIATED WITH LIMITED UTILIZATION

A range of factors have thwarted attempts at promoting female condoms and sustaining their use. The following have all been cited as the basis for the female condom’s continued struggle:

- high cost;
- regular stock outs;
- the lack of reliable distribution systems;

- provider bias and deficient training;
- negative perceptions on the part of funders and policy-makers; and
- the consequent lack of investment in early introduction efforts—particularly the failure to invest as much in programming to build familiarity, trust and acceptance of the new product as in the purchasing of the condoms, themselves.

Each of these, to varying degrees, contributed to lack of uptake.

High cost

Cost is often cited as the chief barrier to scale-up. At introduction, the worldwide retail price of the female condom ranged from US \$2-3 per condom (Frost, Reich & Pratt, 2008; Peters et al., 2010). By contrast, the average retail cost of a male condom is US \$0.03 (UNAIDS Inter-Agency Task Team on Gender and HIV/AIDS; n.d.). The bulk pricing for female condoms (i.e., the price paid by UNFPA and other public donors) is almost 30 times higher than the bulk price for male condoms (Peters et al., 2010). From both a consumer and public health programming perspective, this puts female condoms at a grave disadvantage.

Wider distribution and demand, along with increased competition (as additional female condom models enter the market) should lower the overall cost (Forbes, 2012).

The FHC currently has a monopoly on female condom sales in the US (as no other product yet has FDA approval) and a virtual monopoly in most other markets, as it is producing the vast majority of female condoms used globally. This has somewhat stalled the tendency of market forces to bring prices down as demand goes up. As Peters et al. (2010, p. 125) note:

“...the cost of the female condom has been caught in a vicious circle – perceived low

demand, perceived low acceptability, unwillingness of public policymakers to invest in female condom production, purchase and programmes, stock-outs, high prices and frustrated demand. The result is a stalemate.”

It appears that this stalemate can only be broken by WHO’s pre-qualification approval of additional brands (which is expected to occur within the next two years) and active promotion of female condoms to drive up demand for them.

Meanwhile, in response to the high cost, some women have turned to reusing female condoms to make them more affordable. While the WHO does not recommend the reuse of female condoms due to concerns that reuse could weaken the condoms, it did publish a draft protocol in 2002 that includes guidance for reuse based on studies showing the safety of reuse (Guttmacher Institute, 2001; WHO, 2002). Further studies and official guidelines for the safe reuse of female condoms could help to lower the cost and increase accessibility.

Stock outs and the lack of reliable distribution systems

In many places, the availability of female condoms is often uncertain and unreliable. Whether demand is needed to drive the creation of an affordable supply (or an increasingly affordable supply) of products that will drive increased demand, the fact remains that female condoms currently constitute just over one percent of all condoms distributed worldwide (Forbes, 2012). In 2009, only one female condom was available for every 36 women (Forbes, 2012; UNFPA, 2011). While this is fueled in part by the high cost of female condoms, it is also compounded by the obstacle course created by unreliable or ill-conceived distribution systems (Warren & Philpott, 2003) and the frequent failure of governments and other funders to recognize that male and female condoms are not interchangeable (a mistake that leads them to favor purchasing male

condoms as the cheaper alternative). This misperception misses the unique benefit that female condoms provide to women – an increased ability and opportunity to instigate condom use.

Lack of investment and institutional support

Twenty years after their initial introduction, female condoms still do not enjoy a place on the WHO's essential medicines list. The essential medicines list serves as a guide for national and institutional lists of those medicines required for the successful functioning of a health system and that address the priority health care needs of the population (WHO, n.d., "Access, quality and rational Use," para. 2).

"Lists of Essential Medicines also guide the procurement and supply of medicines in the public sector, schemes that reimburse medicine costs, medicine donations, and local medicine production. Many international organizations, including UNICEF, UNHCR and UNFPA as well as nongovernmental organizations and international non-profit supply agencies, have adopted the essential medicines concept and base their medicine supply system mainly on the Model List."

Female condoms have also received mixed support from international donors. For instance, neither the United States Office of the Global AIDS Coordinator nor the United States Agency for International Development (USAID) directly funds female condom programming. While USAID in-country missions are able to receive technical assistance and support for female condom programs through the President's Emergency Plan for AIDS Relief (PEPFAR), missions have to proactively request the support (CHANGE, 2011). The failure of the US government to demonstrate institutional leadership for the female condom has compounded the lack of on-the-ground support by donors and public health programmers. Countless stories abound of USAID missions

failing to back female condom programming and promotion efforts, going so far as citing a lack of civil society demand for female condoms, even when advocacy groups are beseeching them to support female condom expansion (CHANGE, 2011). Apart from overarching bias and negative perceptions around the female condom, this phenomenon is in large part due to the missions' insufficient engagement with civil society groups in-country (CHANGE, 2011).

Provider bias and deficient training

The lack of support for, and promotion of, female condoms among healthcare providers has been reported in several studies and anecdotal reports, across various locations (Peters et al., 2010). Particularly in low-resource settings, some providers lack the training to educate their patients appropriately about female condoms. Some lack supplies (e.g. pelvic models) to demonstrate use, and others express concerns about stock outs and the inconsistency of supply (Peters et al., 2010). But these are not the only barriers. Some health providers are biased against the female condoms or are inhibited about discussing sex explicitly with their patients, and consequently are uncomfortable initiating discussion of women's HIV prevention options. (Peters et al., 2010). With proper education and training, providers can overcome personal biases and/or limitations and develop the capacity to properly educate and encourage their clients to try new HIV prevention tools.

Negative perceptions

Since its introduction, the female condom has been plagued by an onslaught of negative attitudes and perceptions. At best, there is a persistent myth (debunked to some degree by acceptability research) that women do not accept nor do they like

female condoms (Peters et al., 2010). At worst, female condoms are presented in some settings as a tool of promiscuity or a joke (Kaler, 2004a). The female condom has been dismissed as weird-looking, noisy, or irrelevant because (some argue) women have little say over what happens with their bodies and that dynamic is immutable (Peters et al., 2010).

Some of these negative perceptions arose from the inadequate ways in which female condoms were initially introduced and (in some places) continue to be programmed. In some settings, they were “targeted only at sex workers in the belief that only sex workers can take protection into their own hands. Targeting sex workers might have led to stigmatisation rather than normalisation of the product” (Peters et al., 2010, p. 122). In some areas, due to the challenge female condoms pose to traditional gender norms, they have become associated with promiscuity and infidelity (Feldblum, 2001).

The media in particular has played a role in fueling negative attitudes around the female condom, but so too have international public health experts by their blatant failure to give adequate attention and space to such a promising prevention technology (Kaler, 2004a; Peters et al., 2010).

Failure of early introduction efforts

Generally speaking, early female condom introduction efforts failed to identify target audiences carefully, train providers adequately, or engage in outreach to potential users (Warren & Philpott, 2003). Such efforts were typically undertaken without either adequate funding or strategic planning and handled as “procurement exercises” in which available resources were used to purchase and distribute female condoms at random (Warren & Philpott, 2003, p. 131). Most failed to draw on best practices for

introducing a new product into an existing method-mix, such as the inclusion of hierarchical counseling and outreach to men (NAM, n.d.a). While the female condom is designed as a female initiated method, the reality is most women do not hide it from their partner(s) and male cooperation is necessary (Hoffman et al., 2004). Involving men not only supports effective product use (e.g. so that penile insertion into the condom, not around the condom, is assured), it also enhances the likelihood of couples communicating more easily about sex and negotiated protection. But little attention has been paid in most settings to the need to direct information to male partners and encourage open communication between partners about protection (Frost, Reich & Pratt, 2008).

Each of these factors—regular stock outs, unreliable distribution, a lack of provider training, high-cost, provider bias, negative perceptions and lack of investment—are not independent of one another. Instead, these factors interact, collectively fueling the failure of female condom uptake. The common thread, with the possible exception of its high-cost, is that most of the factors the female condom faces are a direct result of the failures of its early introduction.

CASE STUDIES: THE SUCCESS AND FAILURE OF FEMALE CONDOM PROMOTION

Over the past 20 odd years, the female condom has been introduced throughout the developed and developing worlds. Today, according to UNFPA (2011, p. 12), “the female condom is available in more than 90 countries through public health programmes and is commercially marketed to consumers in ten of those countries.”

While the context and experience of each differs, most countries have not achieved widespread use of the female condom. This experience is not unique to the developed or developing world. Rather, while a handful of countries can be held up as success stories, the majority of female condom introduction efforts have, effectively failed. For a more in-depth examination of how introduction efforts can lead to a NPT's success or failure, we turn to three individual cases spanning both developing countries and the developed world: South Africa, Zimbabwe and the United States.

South Africa

South Africa is often heralded as a major example of a female condom success story. It is also (not coincidentally) one of the few countries in the world where a national family planning program played a central role in introducing female condoms (FHI360, 2007; Peters et al., 2010). Developed over the course of three years, South Africa's introduction strategy was crafted jointly by the National Department of Health, the Reproductive Health Research Unit, and government staff in each of the country's nine provinces (FHI360, 2007; Warren & Philpott, 2003). The project's aim was to integrate female condoms into the country's reproductive health program, as well as its HIV/AIDS program (Warren & Philpott, 2003). Additional partners included FHI360, the Female Health Company and Foundation, UNFPA and the South African National Department of Health. These groups worked together to manufacture and purchase the female condom, distribute them in-country and provide the technical support and training necessary for successful introduction and sustained use.

This multi-sectoral collaboration was key to the success of its program (FHI360, 2007; Peters et al., 2010). Additional support was provided by various social marketing

organizations—namely PSI and the Society for Family Planning—that advertised and distributed female condoms through pharmacies and other commercial outlets (Peters et al., 2010; Warren & Philpott, 2003).

With the intention of both promoting female condoms to a wide audience and avoiding stigmatization, the product was first introduced in 1998 through family planning clinics and community based programs (instead of directly to high-risk groups) (Warren & Philpott, 2003). Introduction programs were characterized by provider training and train-the-trainer efforts that covered a range of contraceptive and STI prevention methods as well as communication, counseling, and the teaching of negotiation skills (FHI 360, 2007; Warren & Philpott, 2003). As a compliment, program planners conducted outreach—including workplace outreach—to target high-risk populations who do not typically attend the traditional health services where female condom programs were being launched (Warren & Philpott, 2003).

After the initial period of introduction, concentrated at 31 pilot sites, South Africa expanded public distribution and promotion of the female condom. By 2005, its female condom program was operating from 204 sites including additional public health clinics, workplaces, truck stops, brothels, and universities (FHI360, 2007; Warren & Philpott, 2003).

Perhaps the most impressive element of South Africa's female condom program has been their evaluation of early stages, prior to expansion. In 1998 and 2000, before expansion of the program, a study was conducted to assess user and provider opinions of female condoms, patterns of use, and potential barriers to integration (FHI360, 2007; Warren & Philpott, 2003). The study found that female condoms complemented male

condom use, that women felt more empowered, and that providers were overwhelmingly supportive of female condom integration (FHI360, 2007; Warren & Philpott, 2003). Some barriers to integration were also uncovered. The most notable of these barriers were a lack of time to counsel and demonstrate use, inadequate inventory management and shipping delays, and a suspension of distribution when responsible staff were absent (FHI360, 2007). Female condom planners used these findings to inform the expansion of their promotion and distribution efforts.

South Africa's female condom program is marked by its strong national leadership, early and comprehensive provider training, proactive introduction strategy, and early stage evaluation efforts conducted prior to program expansion. Further, by partnering with family planning services, the program was able to minimize stigma and optimize limited resources while building a program that could be sustained long-term (Warren & Philpott, 2003).

Zimbabwe

Local advocacy played a key role in the successful introduction of female condoms in Zimbabwe (Meekers, 1999; Warren & Philpott, 2003). Faced with rising rates of HIV, particularly among women, HIV and women's health activists began organizing discussions of women in order to encourage them to protect themselves (Ray et al., 1995). Discouraged by what seemed to be the impossibility of negotiating male condom use with their partners, those involved saw female condom as a source of new hope for women in Zimbabwe (Ray et al., 1995). Similar to many places, male condoms are highly stigmatized in Zimbabwe. Seen as the mark of promiscuity and mistrust or an admission of HIV infection, condoms are most often used in casual

relationships and/or with commercial sex workers (Warren & Philpott, 2003). Female condoms offered an alternative—a new method free from any legacy of stigma.

In 1996, women's health activists, led by the Women and AIDS Support Network, organized a public march to petition the MoH and the National AIDS Control Programme to make the female condom widely available (Meekers, 1999; Peters et al., 2010). They were successful in garnering government support and regulatory agency approval. In 1997, Zimbabwe launched what is now held up as an example of a successful female condom program (Kerrigan et al., 2000; Warren & Philpott, 2003). As in South Africa, this success is generally attributed to the collaboration between a range of public and private stakeholders and the strategic implementation of a comprehensive program to introduce female condoms into the public health sector (Hoffman, et al. 2004; Peters et al., 2010). Among other benefits, strong leadership from the MoH helped to ensure inclusion of the female condom in the National AIDS Control Programme and budget, prerequisites for continued funding and access (Warren & Philpott, 2003). In at least one post-marketing survey, more than half of the female condom users surveyed indicated they had heard of the device from a health provider, highlighting Zimbabwe's success in provider outreach and training, including training for pharmacists and community based organizations (Hoffman et al., 2004; Kerrigan et al., 2000).

Given the high levels of stigma attached to the male condom in Zimbabwe, program planners—most notably PSI—commercially marketed the female condom primarily to married women as a contraceptive sheath under the brand name Care™ to draw attention to its capacity for contraception, rather than disease prevention (Warren

& Philpott, 2003). The condoms were sold at clinics, pharmacies and other commercial outlets at a heavily subsidized price of US\$0.24 (Kerrigan et al., 2000). At the same time, the government launched a public sector female condom program to reach rural and high-risk communities (Warren & Philpott, 2003).

Early evaluation efforts made it possible for Zimbabwe's female condom program to be continuously adapt based on feedback received from users and providers, ensuring the continued relevance of its promotion efforts (Warren & Philpott, 2003). Approximately one year into Zimbabwe's female condom introduction program, PSI and the Horizons Project conducted a cross-sectional study of female condom users, male condom users and those not using either method in order to better understand the dynamics of female condom use and strengthen Zimbabwe's female condom program (Kerrigan et al., 2000). Likewise, UNFPA's later efforts were informed by evaluations of past programs and potential barriers to use (UNFPA, 2011).

Alongside the government's efforts, women's health and HIV groups organized education programs, furthering female condom promotion across the country (Peters et al., 2010). Using a comprehensive social marketing strategy and the public health practice of using community-based distributors for health services, female condom programmers in Zimbabwe also tapped into existing social structures and norms, training 2,070 hairdressers and barbers to act as female condom educators and distributors (Bertrand, Pineda, Santiso & Hearn, 1980; UNFPA, n.d.; UNFPA 2011). In addition, well-crafted social marketing campaigns that utilized TV, radio and billboards, helped to escalate female condom distribution in both the public and private sectors, increasing its uptake from an estimated 1.3 million condoms in 2005 to more than 5

million in 2008 (UNFPA, 2011). This success also resulted in a drop in female condom pricing (CHANGE, 2011). When the female condom was first marketed in Zimbabwe the unit cost was US \$4.50 (CHANGE, 2011). However, as Zimbabwe expanded its program and demand increased, the price dropped to under US \$1 (CHANGE, 2011).

Advocacy, social marketing, and community-based outreach are the hallmarks of Zimbabwe's female condom story. Government leadership and a commitment to implementing, monitoring, and evaluating a proactive strategy that integrated female condoms into existing services worked to ensure its success (Hoffman et al., 2004).

United States

After its initial introduction in Europe in 1992 and FDA approval in 1993, the female condom was first introduced in the United States in the mid-1990s. Faced with limited capacity and resources, the Female Health Company had to make choices about where to focus its efforts. The company concentrated its efforts toward promoting and distributing the female condom in the developing world through their partnerships with the public health sector (Female Health Company, n.d.). While social marketing campaigns are routinely used to introduce new public health interventions, the Female Health Company wrongly assumed that if the female condom was simply made available—without social marketing efforts—Western women would readily use it. Under this logic the manufacturer simply put the female condom on drug store and clinic shelves in much of North America and Europe with little, if any, intentional effort to introduce the product (Peters et al., 2010). What US consumers saw was a completely unfamiliar device with a high price tag and no complementary programming explaining its potential benefits.

As a result, unlike its counterparts in South Africa and Zimbabwe, US introduction was characterized by inadequate provider training, limited distribution within the public health system, inadequate advertisement and promotion and, perhaps most notably, ridicule of the female condom in the press (Hoffman et al., 2004). As Amy Kaler (2004a, p.142-43) recalls in *The Female Condom in North America: Selling the Technology of 'Empowerment'*:

"It was constructed as a ridiculous device, a ludicrous insult to the sensibilities of any woman foolish enough to use it...Negative press reports ridiculed the female condom comparing it to, among others, a jellyfish, a windsock, a fire hose, a colostomy bag, a Baggie, gumboots, a concertina, a plastic freezer bag, something to line Boston's Inner Harbor with...Even writers who acknowledged the female condom a possible means of empowering women claimed that it would be doomed by its weirdness."

Not surprisingly, the female condom—sold initially under the brand name "Reality"—did not enjoy success in the US market. Six years after its initial introduction less than one percent of American contraception users were using female condoms (Kaler, 2004a). While the method appealed to women's health advocates and found some distribution success in programs responding to poverty and addiction among women, the device never seemed to find traction among the mainstream (Kaler, 2004a). Without active promotion, provider training or strategies on how to best target US consumers, the negative press doomed the female condom to years of mocking and limited use.

Unfortunately, the US experience has been echoed throughout much of the world with either negative perceptions or ignorance of the female condom being the product's main trademarks. In the only study conducted in Italy on female condom use and

preference, only one fourth of the 162 men and women participating in the study had ever heard of the female condom (Spizzichino et al., 2007). In Kenya, while female condoms are officially part of the country's HIV and family planning programs, "women have shown little interest [and] overall the demand is low due to general unavailability and [lack of] information" (PlusNews, 2011).

However, thanks to renewed energy and efforts on the part of HIV and women's health advocates, the improved design of the FC2, and increased involvement from the Female Health Company, the female condom is starting to gain some ground in the US and other markets. In recent years the Female Health Company has begun creating public-private partnerships to promote the female condom in key cities throughout the US (Frank, 2012). In Washington, DC—the city with the highest HIV prevalence in the country—the Female Health Company has partnered with the D.C. Female Condom Initiative, a coalition that includes the district's health department and various community based organizations. Based on lessons learned from introduction efforts in Zimbabwe, the DC campaign focuses primarily on education and training including the use of peer educators (Frank, 2012). In other major cities, with the help of the Female Health Company, health departments and advocacy groups have begun efforts to increase awareness and uptake of the female condom, sponsoring education seminars for health educators and launching awareness campaigns (NAM, n.d.b). US female condom advocates are also getting help from another source—African HIV prevention advocates and coordinators from countries such as Malawi who have begun travelling to the US to help educate American providers in female condom promotion and use (NAM, n.d.b).

However, despite these renewed efforts, female condoms remain unaffordable for many potential users, are difficult to access in some areas, and are continuously challenged and under-promoted due to provider bias and negative perceptions. What's more, while the United States case study offers a striking contrast to the experiences of South Africa and Zimbabwe, it is much more representative of the overall female condom experience. Whereas Brazil, Ghana, India, South Africa and Zimbabwe are often heralded as examples of female condom success, the reality is female condom introduction efforts have not resulted in high uptake of the device in the majority of markets (Frost, Reich & Pratt, 2008; Peters et al., 2010; Peterson et al., 2008). With the bulk of female condoms being distributed by public health and family planning agencies throughout the developing world—most notably Africa—traditional commercial sales and national public distribution efforts outside those agencies' priority areas have generally suffered (Peterson et al., 2008).

LESSONS LEARNED

While the majority of efforts around introducing, promoting and sustaining interest in the female condom have fallen short, the few success stories offer important insights on how program planners can better prepare for future introduction efforts around new prevention technologies. According to Warren and Philipott (2003, p. 130), in addition to strong leadership and the involvement of a range of stakeholders, female condom successes, "have several key similarities: a focus on training for providers and peer educators, face-to-face communication with potential users to equip them with information and skills, an identified target audience, a consistent supply, a long

assessment period to gauge actual use beyond the initial novelty phase, and a mix of public and private sector distribution.”

While there is much to be learned from successful cases like South Africa and Zimbabwe, we can draw equally important lessons from the common barriers to access and use that characterized much of the female condom’s early introduction, and the disappointing experiences of places like the US.

From an assessment of the early introduction efforts around the female condom and the key case studies of South Africa, Zimbabwe and the United States, the HIV prevention field should consider the following lessons as they move toward the introduction of a range of new prevention technologies.

Strategically plan and design introduction programs

Proactive strategies that employ a comprehensive approach, are informed by the local context, and identify the best way(s) to position a NPT are crucial for their successful introduction and sustained use. In order to plan strategically, UNAIDS and WHO (2000) recommend considering the following elements within the broader socio-cultural, political and resource contexts of the area(s) in which introduction efforts are taking place:

- the needs of potential users,
- the services and technologies currently available, and
- the capability of the service delivery system.

As highlighted in the US case study, introduction cannot simply consist of making the new method available on pharmacy shelves. Instead, it requires the active and thoughtful promotion of the product to targeted groups through a variety of strategies

and distribution channels including active promotion at those sites, including client counseling (UNFPA, WHO & PATH, 2005). Where this is not possible, program planners should at the least, “display and distribute educational materials in order to give essential information on correct use of the product” (UNFPA, WHO & PATH, 2005, p. v).

In the best case scenario, it includes the support and active leadership of a wide range of stakeholders including donor agencies, national governments, community leaders, service providers and advocacy groups (Warren & Philpott, 2003). As Warren and Philpott (2003, p. 135) note, “NGOs, community-based organizations and especially women’s organisations...have been the lead advocates for the establishment of female condom programmes. They have mobilised government and donor support to introduce the female condom, placed the female condom within the larger context of overall community priorities, and promoted increased access to and acceptability of the female condom within the community in the context of broader cultural and political issues.”

Engage communities and advocates

As stated, fostering a supportive environment is vital for the success of any introduction effort (UNFPA, WHO & PATH, 2005). “People are far more likely to use condoms if they perceive that the beliefs and behaviors of their partners, friends, peers the immediate community, and broader society favour safer sex practices. Thus, condom programming should address the broader community and the political and sociocultural environment as well as individual clients” (UNFPA, WHO & PATH, 2005, p. 61).

To effectively do this, program planners need to include a wide range of

stakeholders including key decision makers, service providers, community leaders and relevant advocacy and community-based groups. As UNAIDS and WHO (2005, p. 25) point out, “doing this from the outset can help to ensure initial acceptance of the method and facilitate the introduction process.” Moreover, involving a wide range of stakeholders facilitates general promotion of the product which can, “help to destigmatize the method and normalize it as a potential method for all sexually active women and men, not just those who engage in high-risk behaviors or are living with HIV or AIDS” (Hoffman, 2004, p. 142).

Carefully select target populations

According to UNFPA, WHO and PATH (2005, p. 10), “effective ‘programming focuses its energy and resources on key client groups’ allowing managers to tailor interventions to clients needs, concerns and special circumstances making them more likely to increase...[NPT] use and reduce HIV transmission.” As such, before activities take place, introduction programs should conduct a comprehensive needs assessment that gathers epidemiological, socio-cultural and behavioral information in order to better understand potential target groups, their needs, preferences, risk factors and possible barriers to use (UNFPA, WHO & PATH, 2005). In this way, social marketing campaigns—including branding—and other introduction efforts can be strategically tailored to unique target groups, increasing the likelihood that users will adopt the new technology.

Focus on education and training

In their review of female condom introduction efforts, Frost, Reich and Pratt (2008, p. 185) note that, “well designed and implemented training programs and

materials can significantly increase adoption.” Comprehensive training and education programs include (Frost, Reich & Pratt, 2008; Warren & Philpott, 2003):

- training for providers to ensure that possible provider biases do not negatively influence potential users;
- training for providers to ensure a client-centered approach where clients choose products most appropriate for their personal needs and preferences;
- training for providers, pharmacists, peer educators and other distributors to ensure they can effectively counsel on and demonstrate use of the product, teach negotiation and partner communication skills and answer questions about sexuality and anatomy;
- face to face education at distribution sites to equip potential users with information and skills; and
- user-friendly promotion and education materials.

Training for service providers is a key component of the training and education needed for successful introduction. Evidence points not only to the positive role that service providers can play in introducing a new prevention technology but that, without adequate training, they can actually undermine promotional efforts, effectively marginalizing the product (Hoffman, 2004). On the other hand, adequate training and education for service providers can help to recruit them as partners in the introduction, ensuring they have accurate knowledge, good counseling skills and positive attitudes (UNFPA, WHO & PATH, 2005).

Integrate NPTs into existing health services and programs

One key element from the female condom success stories, including South Africa and Zimbabwe, was the integration of female condom interventions into existing health programs, namely family planning and HIV/AIDS prevention services (Warren & Philpott, 2003). Similar integration strategies have also proven effective in introducing new contraceptive methods (UNAIDS & WHO, 2005). By integrating introduction efforts into established health programs, program planners can capitalize on the success and structure of existing services. By introducing products into varied programs, for instance family planning, maternal health and HIV prevention programs, planners can expand their reach and help to further generalize the technology.

Ensure strong leadership

As Frost, Reich & Pratt (2008, p. 185) observed, “a major barrier to female condom access has been the absence of an effective global architecture and champion.” From ensuring affordable pricing and reliable distribution to developing strategic introduction and scale-up programs, leadership—particularly that of donors and governments—is crucial for the success of any new prevention technology (Warren & Philpott, 2003; UNAIDS & WHO, 2005). Strong leadership is also required to (Frost, Reich & Pratt, 2008):

- develop political and social support;
- increase public and private sector investment;
- move beyond the pilot stage to scale up; and
- to conduct research to improve programming, including operational research to identify behavior change strategies and evaluations of long-term impacts.

In addition to leadership from governments, donors and the international community, female condom programmers have also repeatedly stressed the importance of, “cultivating key individuals as advocates...and nearly all mentioned the role of one or more charismatic leaders as having been key to...promotion, whether at global, national or local levels” (Kaler, 2004b, p. 505). This kind of leadership will prove just as crucial for the introduction of NPTs as it was for the female condom.

Address cost

In almost all reviews of the female condom, the high cost of the product is cited as a major barrier to widespread use and the scaling up of programs (Kaler, 2004b). More than twenty years after its initial introduction, the female condom remains an expensive commodity compared with the male condom for three main reasons, “the raw material is expensive;...the manufacturing technology of female condoms is more expensive and complex[than that of the male condom; and]...the overall volume of female condoms sold is...[low]” (Warren & Philpott, 2003, p. 136).

Before NPTs are introduced, and arguably as early as the formulation stage, the end cost should be a consideration. Even if a technology were found to be 100 percent effective at preventing HIV, if it was unaffordable for the majority of users it would have no significant impact in overall HIV rates. From the outset, researchers and other stakeholders should ensure the affordability of NPTs by:

- selecting inexpensive materials,
- exploring ways to introduce competition into the market,
- investigating manufacturing capabilities and cost-effectiveness, and

- beginning discussions with donor and public health agencies about bulk and/or public sector pricing (Frost, Reich & Pratt, 2008).

Expand distribution systems

The most successful female condom introduction programs were those that used a mix of public and private sector distribution channels, including the use of nontraditional channels (such as taxi stations and barber shops) through which to promote and distribute the product (Frost, Reich & Pratt, 2008; Warren & Philpott, 2003). Some of the more traditional distribution channels that proved effective for successful female condom programming include, “commercial sales, social marketing, community-based distribution, and workplace promotion as well as the health care system” (UNFPA, WHO, PATH, 2005, p. 49).

In order to expand a technology’s use and reach new client groups, program planners should employ multiple distribution channels, increase the number and types of distribution outlets, and match those outlets to the needs of their target populations (UNFPA, WHO & PATH, 2005). In addition, “to ensure a reliable and consistent supply of condoms—and thus avoid shortages, stockouts and oversupply—quality monitoring must occur at every stage so that all elements of the system operate effectively” (UNFPA, WHO, PATH, 2005, p. 33). To this end, program planners should implement quality control measures such as a Logistics Management Information System (LMIS) to collect and report data about “distribution, monitor stock levels, and make informed decisions about product selection, forecasting, procurement, and inventory management” (UNFPA, WHO & PATH, 2005, p. 33).

Engage users’ sexual partners

Another major lesson learned from the female condom experience is the importance of engaging end users' sexual partners, in the case of the female condom, men. In fact, according to Warren and Philpott (2003, p. 137), while "women have typically been the target audience for the promotion of female condoms,...in many countries men still maintain the dominant role in sexual decision-making, including decisions related to contraception and prevention of STI/HIV. Targeting men in promotion and education has proven effective in improving overall acceptability of the method." Involving partners in product promotion can be particularly effective in cultures where women have limited power and status (Frost, Reich & Pratt, 2008). Some programs have employed the use of trained male health educators to serve as role models, reasoning that, "men are more likely to respond to prevention messages if their male peers are also doing so" (UNFPA, WHO & PATH, 2005, p. 65).

As the HIV prevention field begins discussing introduction strategies around a range of potential NPTs, how to actively involve the sexual partners of end users will be a crucial element.

Evaluate and redesign programs

A well developed monitoring and evaluation (M&E) plan, implemented from the start, is one of the keys to successfully introducing a NPT. In fact, in terms of female condoms, one of the elements that led to success in places like South Africa and Zimbabwe was the use of a "long assessment period to gauge performance of the distribution programme and to measure use of the female condom over time, not just during the novelty stage at programme inception" (Warren & Philpott, 2003, p. 131). This kind of M&E plan allows program planners to, "detect and fix problems, assess

program performance, and decide which activities to expand or stop” (UNFPA, WHO & PATH, 2005). To be effective, M&E systems, “should measure inputs (the number of people trained in condom counselling and distribution), outputs (the availability and quality of...[the NPT]), outcomes (changes in...[product] use and sexual behaviour) and impacts (changes in HIV and STI rates)” (UNFPA, WHO & PATH, 2005, p. v).

Evaluation efforts should take the long-view, in particular, to account for the time needed to demonstrate a meaningful impact. In the case of the female condom, some of the evaluation efforts have come under criticism for being too short to effectively evaluate the product’s success:

“Typically, interventions were evaluated after only one to three years. The benefits of having female condoms available, however, might take many more years to show up, especially when these benefits took the form of broader societal changes in attitudes towards sexuality or in women’s knowledge of and thus their control over their bodies...Positive changes may take decades to show up, as in the case of tampons, for example, or the slow uptake of male condoms. Beyond this, they should not look for ever-growing numbers of users, instead they should look at the number of potential infections averted” (Kaler, 2004, p. 513).

LESSONS THAT NEED TO BE STUDIED FURTHER

While the various limiting factors and individual case studies explored in this paper offer important lessons for the introduction of future prevention technologies, a few key lessons warrant further study.

- What factors limited the Female Health Company’s ability to effectively advertise, promote and increase support of the female condom?

- What is the association between availability of national health care and use of female condoms?
- What is the association between the use of male condoms and use of female condoms (i.e., in countries where there is less of a stigma around the use of male condoms is there lower use of female condoms due to higher male condom use)?

Exploration of these issues may help to further inform successful introduction strategies for new prevention technologies and avoid some of the pitfalls experienced by the female condom.

CONCLUSION

More than twenty years since their initial introduction female condoms remain marginalized, suffering from low uptake, high-cost, a lack of recognition and negative perceptions. While there are a handful of success stories we can point to, the overall experience of female condoms is best described as a missed opportunity for the HIV and STI prevention and family planning fields—one that can hopefully be rectified by the recent resurgence of advocacy efforts around increasing awareness of and access to the product.

While the case studies of Zimbabwe, South Africa and the US each have unique elements, the stories of their successes and failure are characteristic of the range of female condom introduction efforts. What's more, the factors that led to the high uptake and sustained use of female condoms in places like South Africa and Zimbabwe, and

their marginalization in the US, are directly applicable to the range of NPTs—including microbicides, PrEP and vaccines—that are currently in the research pipeline.

As public health practitioners begin planning for the introduction of this new range of HIV prevention technologies, they would do well to examine lessons from the female condom experience. Specifically, program planners should take the time to thoughtfully and strategically plan and design future introduction programs for NPTs that include:

- engagement with communities and advocates,
- careful selection of target populations,
- a focus on education and training, including that of end users' sexual partners,
- integration of NPTs into existing health services and programs,
- strong leadership,
- negotiations around the end cost of products,
- varied distribution systems, and
- ongoing efforts to monitor and evaluate programs, with a commitment to redesigning them when necessary.

While further examination of some key issues is needed, the lessons outlined here provide a base of knowledge the public health field can use to implement informed introduction efforts in order to better guarantee the ability of NPTs to increase protection and reduce the overall incidence of HIV.

REFERENCES

- Artz, L., Macaluso, M., Brill, I., Kelaghan, J., Austin, H., Fleenor, M., Robey, L., & Hook, E.W. (2000). Effectiveness of an intervention promoting the female condom to patients at sexually transmitted disease clinics. *American Journal of Public Health*, 90(2), 237-44.
- Bertrand, J.T., Pineda, M.A., Santiso, G.R., & Hearn, S. (1980). Characteristics of Successful Distributors in the Community-Based Distribution of Contraceptives in Guatemala. *Studies in Family Planning*, 11(9-10), 274-285.
- Center for Health and Gender Equity. (n.d.). *Female Condoms, Products*. Retrieved February 21, 2013 from, http://www.preventionnow.net/female_condoms/products/.
- Center for Health and Gender Equity. (2011). *Female Condoms and U.S. Foreign Assistance: An Unfinished Imperative for Women's Health*. Washington, DC: CHANGE.
- Feldblum, P. (2001). The Female Condom: Beyond Acceptability to Public Health Impact. *Sexually Transmitted Diseases*, 28(11), 655-657.
- The Female Health Company. (n.d.) Retrieved February 13, 2013 from, <http://www.femalehealth.com/>.
- FHI360. (2007). *Female Condom Introduction in South Africa* (Female Condom Research Brief Series No. 6). Durham: FHI360.
- Forbes, A. (2012, June). *Female Condoms: The Basics*. Presented at the Universal Access to Female Condom Joint Programme DC Volunteer Training, Washington, DC.

Frank, M.M. (2012, December 1). Case in Point: Marketing the female condom. *The Washington Post*. Retrieved from http://articles.washingtonpost.com/2012-12-01/business/35585857_1_female-condom-mary-ann-leeper-innovation.

Frost, L.J., Reich, M.R. & Pratt, B.A. (2008). Female Condoms: Access to Dual Protection Technologies. In Frost, L.J. & Reich, M.R. (Eds.), *Access: How Do Good Health Technologies Get to Poor People in Poor Countries?* (pp. 167-197). Cambridge: Harvard University Press.

The Global Coalition on Women and AIDS. (n.d.). *Basic Facts on the Female Condom*. Retrieved February 8, 2013 from, http://data.unaids.org/GCWA/gcwa_bg_femalecondom_en.pdf.

The Gray Sheet. (1993, May 17). Wisconsin Pharmacal Reality Female Condom: Limited Shipments Will Begin. *Elsevier Business Intelligence*. Retrieved from <http://www.elsevierbi.com/publications/the-gray-sheet/19/020/wisconsin-pharmacal-reality-female-condom-limited-shipments-will-begin?targetAN=01190200005>.

Guttmacher Institute. (2001). Female Condoms Remain Structurally Sound After Being Washed and Reused as Many as Seven Times. *Family Planning Perspectives*, 33(4).

Hoffman, S., Mantell, J., Exner, T. & Stein, Z. (2004). The Future of the Female Condom. *International Family Planning Perspectives*, 30(3), 139-145.

Joint United Nations Programme on HIV/AIDS and World Health Organization. (2000). *The Female Condom: A guide for program and planning*. Geneva: UNAIDS and WHO.

Joint United Nations Programme on HIV/AIDS. (2012). *Global report: UNAIDS report on the global AIDS epidemic 2012*. Geneva: UNAIDS and WHO.

Kaler, A. (2004). The Female Condom in North America: Selling the Technology of ‘Empowerment’. *Journal of Gender Studies*, 13(2), 139-152.

Kaler, A. (2004). The Future of Female-Controlled Barrier Methods for HIV Prevention: Female Condoms and Lessons Learned. *Culture, Health & Sexuality*, 6(6), 501-516.

Kerrigan, D., Mobley, S., Rutenberg, N., Fisher, A. & Weiss, E. (2000). *The Female Condom: Dynamics of Use in Urban Zimbabwe*. Washington, DC: Population Council.

Meekers D. (1999). *Patterns of Use of the Female Condom in Urban Zimbabwe*. Washington, DC: Population Services International.

NAM. (n.d.) *Acceptability and usage*. Retrieved February 1, 2013 from, <http://www.aidsmap.com/Acceptability-and-usage/page/1746291/>.

NAM. (n.d.). *Providing and promoting the female condom*. Retrieved March 17, 2013 from, <http://www.aidsmap.com/Providing-and-promoting-the-female-condom/page/1746299/>.

PATH. (n.d.) *A unique kind of condom: Woman’s Condom expands choices for protection*. Retrieved February 21, 2013 from, http://www.path.org/projects/womans_condom.php.

Pathfinder International. (n.d.). *Why Choice Matters*. Retrieved February 13, 2013 from, <http://www.pathfind.org/>.

- Peters, A., Jansen, W. & van Driel, F. (2010). The female condom: the international denial of a strong potential. *Reproductive Health Matters*, 18(35), 119-128.
- Population Council & Liverpool VCT, Care & Treatment. (2009). *Female-initiated prevention: integrating female condoms into HIV risk-reduction activities in Kenya*. Nairobi: Population Council.
- Ray, S., Bassett, M., Maposhere, C., Manangazira, P., Nicolette, J.D., Machekano, R. & Moyo, J. Acceptability of the Female Condom in Zimbabwe: Positive but Male Centered Responses. *Reproductive Health Matters*, 3(5), 68-79.
- Spizzichino, L., Pedone, G., Gattari, P., Luiz, A.M., Gallo, P., Valli, R. & Rezza, G. (2007). The female condom: knowledge, attitude and willingness to use. The first Italian study. *Anna Is Super Sannita*, 43(4), 419-424.
- UNAIDS Inter-Agency Task Team on Gender and HIV/AIDS. (nd). HIV/AIDS, Gender and Male and Female Condoms. Retrieved March 17, 2013 from, http://www.unfpa.org/hiv/docs/factsheet_condoms.pdf.
- United Nations' Children's Fund. (2011). *The State of the World's Children 2011: Adolescence: An age of opportunity*. New York: UNICEF.
- United Nations Population Fund. (2011). *HIV Prevention Gains Momentum: Successes in Female Condom Programming*. New York: UNFPA.
- United Nations Population Fund. (nd). Preventing HIV Infection. Retrieved March 17, 2013 from, <http://www.unfpa.org/hiv/prevention/hivprev6c.htm>.
- United Nations Population Fund, World Health Organization & PATH. (2005). *Condom Programming for HIV Prevention: An Operations Manual for Programme Managers*. New York: UNFPA.

- U.S. Food and Drug Administration. (2012, July 16). FDA approves first drug for reducing the risk of sexually acquired HIV infection. *U.S. Food and Drug Administration*. Retrieved from <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm312210.htm>.
- Warren, M. & Philpott, A. (2003). Expanding Safer Sex Options: Introducing the Female Condom into National Programmes. *Reproductive Health Matters*, 11(21), 130-139.
- Weller, S.C. & Davis-Beaty, K. (2002). Condom effectiveness in reducing heterosexual HIV transmission. *Cochrane Database of Systematic Reviews*, 1. doi: 10.1002/14651858.CD003255.
- PlusNews. (2011, August 11). HIV/AIDS: Female condoms slowly gaining popularity—Report. *PlusNews*. Retrieved from <http://www.plusnews.org/Report/93476/HIV-AIDS-Female-condoms-slowly-gaining-popularity-report>.
- World Health Organization. (n.d.). *Essential medicines*. Retrieved February 22, 2013 from, http://www.who.int/medicines/services/essmedicines_def/en/index.html.
- World Health Organization. (2002). *The Safety and Feasibility of Female Condom Reuse: Report of a WHO Consultation*. Geneva: World Health Organization.
- Youssef, H. (1993). The history of the condom. *Journal of the Royal Society of Medicine*, 86(4), 226–228.